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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/821,128

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Jun E. Lee

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EXAMINER

SISSON, BRADLEY L

ART UNIT

PAPER NUMBER

1634

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PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/821,128	<b>Applicant(s)</b> LEE ET AL.	
	<b>Examiner</b> Bradley L. Sisson	<b>Art Unit</b> 1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 07 January 2008.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 and 32-82 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,6,8,9,55,59,62,64,65,71,76 and 78 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Continuation of Disposition of Claims: Claims withdrawn from consideration are 2,4,7,10-14,32-54,56-58,60,61,63,66-70,72-75,77 and 79-82.

## DETAILED ACTION

### *Election/Restrictions*

1. Claims 2, 4, 7, 10-14, 32-54, 56-58, 60, 61, 63, 66-70, 72-75, 77, and 79-82 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 30 August 2006.

### *Claim Rejections - 35 USC § 112*

2. The rejection of claims under 35 USC 112, second paragraph, has been withdrawn in view of the amendment to the claims. By clarifying the claims, a new issue under 35 USC 112, first paragraph and under 35 USC 101 is raised

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

5. Claims 1, 3, 5, 6, 8, 9, 55, 59, 62, 64, 65, 71, 76, and 78 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility.

6. As presently worded, the claimed composition fairly encompasses the template, which was elected by applicant to be mRNA; see claims 6, 8, 9, 62, 64, and 65. The aspect of the

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template being present in the composition fairly encompasses mRNA from any source, including expressed sequence tags for which no known utility exist.

7. Applicant is urged to further amend the claims so that they recite mRNA for which adequate support exists and for which utility unquestionably does exist.

8. Claims 1, 3, 5, 6, 8, 9, 55, 59, 62, 64, 65, 71, 76, and 78 are also rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

### ***Claim Rejections - 35 USC § 103***

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

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claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

12. Claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76, and 78 are rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,709,815 B1 (Doug et al.) in view of US Patent 6,906,244 B2 (Fischer et al.).

13. Doug et al., column 44, last paragraph, bridging to column 45, disclose a method by which PCR as well as RT-PCR is performed using mRNA as a template. Doug et al., also disclose that the reaction can be one that incorporates any combination of modified nucleotides. The aspect of Doug et al., performing RT-PCR speaks directly to the presence of an enzyme with reverse transcriptase activity.

14. At page 9 of the response received 07 January 2008, applicant's representative directs attention to column 11, lines 27-30, and to column 12, lines 26-29, as teaching that "a nucleotide analog" is being incorporated not a plurality of nucleotide analogs. (Emphasis in the original.) This argument has not been found persuasive for Doug et al., at column 44, provides a definition for "nucleotide analog" and states that this encompasses both singular and plural uses. Accordingly, the use of the expression "a nucleotide analog" in column 11 does not alter the broader definition provided in column 44. It is further noted that in column 10, Dough et al., teach that probes, which can be the resulting amplicons, "may comprise DNA, RNA, PNA, and combinations thereof as well as comprise modified nucleotides, universal bases, adducts, etc."

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15. Clearly, Dough et al., contemplate the use of any combination of nucleotides in a wide variety of formats.

16. While Doug et al., has been found to disclose using various analogs, including dUTP, they have not been found to teach the use of aminoallyl-dUTP.

17. Fischer et al., column 49, fourth paragraph, discloses using aminoallyl-dUTP in an assay that utilized a reverse transcriptase and mRNA.

18. It is further noted that the reagents, including the aminoallyl-dUTP, were provided in a kit.

19. It would have been obvious to one of ordinary skill in the art at the time the invention was made to have modified the composition of Doug et al., by incorporating aminoallyl-dUTP into same, as disclosed by Fischer et al., as Fischer et al., teaches explicitly of using such to produce transcripts of mRNA and that such can also be provided in a kit.

20. In view of the detailed teachings, and advanced state of the art, said ordinary artisan would have had a most reasonable expectation of success.

21. Accordingly, and in the absence of convincing evidence to the contrary, claims 1, 3, 5, 6, 8, 9, 15, 55, 59, 62, 64, 71, 76, and 78 remain rejected under 35 U.S.C. 103(a) as being unpatentable over US Patent 6,709,815 B1 (Doug et al.) in view of US Patent 6,906,244 B2 (Fischer et al.).

### ***Conclusion***

22. Objections and/or rejections which appeared in the prior Office action and which have not been repeated hereinabove have been withdrawn.

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23. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

24. A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

25. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley L. Sisson whose telephone number is (571) 272-0751. The examiner can normally be reached on 6:30 a.m. to 5 p.m., Monday through Thursday.

26. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla, Ph.D. can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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27. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Bradley L. Sisson/  
Primary Examiner, Art Unit 1634